

Vericom Co. Ltd.

Healthy and beautiful teeth with Vericom

## 510(k) Summary

MAR 16 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: \_\_\_\_\_

## 1. Company making the submission:

Submitter	
Name	VERICOM Co., Ltd.
Address	#606, 5 <sup>th</sup> Dongyoung Venturestel 199-32, Anyang 7-Dong, Manan-Gu, Anyang-Si, Gyeonggi-Do, Republic of Korea 430-817
Phone	+82 31 441-2881
Fax	+82 31 441-2883
Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

## 2. Device :

Proprietary Name – DenFil™ flow

Common Name - Dental Composites and Filling Materials

Classification Name – Material, Tooth Shade, Resin

## 3. Predicate Device : Tetric Flow, IVOCLAR NORTH AMERICA, INC. K993783

## 4. Description :

DenFil™ flow is a light-cured radio-opaque flowable restorative resin. It is composed of Epoxyacrylate(Bis-GMA), Diurethane dimethacrylate, Triethyleneglycol dimethacrylate, Barium aluminosilicate and other materials. As DenFil™ flow has a lower viscosity than paste type composite resin-Flow; 0.16 mm/30sec, so it can restore narrow & deep cavity easily. DenFil™ flow can be applied to fill cavities of all types exactly and efficiently by using a disposable tip. And DenFil™ flow has various shade that correspond to the most common used shading system.

## 5. Indication for use :

- Class V restorations (cervical caries, root erosion, wedge shaped defects)
- Anterior restorations (Class III, IV)
- Small posterior restorations
- Restorative therapy for mini-cavities of all types
- Extended fissures sealings in molars and premolars
- Repair of composite/ceramic veneers
- Blocking out of undercuts

## 6. Review :

DenFil™ flow has the similar technological characteristics as the predicate device; main material, chemical composition, Radiopaque, visible light activate and design.

# 606, 5<sup>th</sup> Dongyoung Venturestel, 199-32, Anyang 7-dong, Manan-gu, Anyang-si, Gyeonggi-do 430-817, Korea



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DenFil™ flow has the similar mechanical properties as the predicate device; compressive strength, flexural strength, flow, film thickness, wear, polymerization shrinkage and thermal expansion coefficient.

DenFil™ flow has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance for the Preparation of Premarket notifications for Dental Composite" and based on the information provided in this premarket notification Vericom Co., Ltd. concludes that DenFil™ flow is safe and effective and substantially equivalent to predicate devices as described herein.

8. Vericom Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 16 2006

Vericom Company, Limited  
C/O Mr. John Howlett  
British Standards Institution  
Product Services  
Maylands Avenue  
Hemel Hempstead  
United Kingdom HP2 4QS

Re: K060637

Trade/Device Name: DenFil™flow  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth shade resin material  
Regulatory Class: II  
Product Code: EBF  
Dated: March 10, 2006  
Received: March 10, 2006

Dear Mr. Howlett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**510(k) Number (if known) K060637

Device Name: DenFil™ flow

## Indications For Use:

- Class V restorations (cervical caries, root erosion, wedge shaped defects)
- Anterior restorations (Class III, IV)
- Small posterior restorations
- Restorative therapy for mini-cavities of all types
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- Repair of composite/ceramic veneers
- Blocking out of undercuts

Prescription Use ☒ AND/OR Over-The-Counter Use ☐  
(21CFR801 Subpart D) (21CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Director, Biotechnology, General Hospital,  
Control, Dental DevicesK060637